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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,555	01/09/2001	Levon Michael Khachigian	273402002020	9700
25226	7590	05/22/2006		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER EPPS FORD, JANET L	
			ART UNIT 1633	PAPER NUMBER

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,555

Applicant(s)

KHACHIGIAN, LEVON MICHAEL

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4-8-03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/142,779
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 103

2. Claims 1-2 and 4-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mendelsohn et al. in view of Sells et al. for the reasons of record.
3. Applicant's arguments filed 2-24-06 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that:

First, Sells et al. does not suggest or provide any one of the specific steps a) to c) of the method claimed. Sells et al. does not relate to the field of vascular diseases or methods of identifying agents that would be useful for treating vascular diseases. In fact, the document relates to the field of tumor biology, in particular the document concerns elucidating the role of Egr-I in melanoma cells.

Second, Sells et al. does not relate to any methods of selecting compounds. Sells does not even provide methods of selecting compounds useful for inhibiting tumor cells. Further, the document does not suggest utilizing Egr-I to select for compounds that can inhibit cell proliferation. Sells et al. is not relevant to the particular field.

Third, Mendelsohn et al. teaches vasoprotective agents that activate estrogen responsive genes in vascular cells. Mendelsohn also teaches vasoprotective agents that inhibit vascular smooth muscle cell activation and/or proliferation or enhance vascular endothelial cell activation and/or proliferation.

Moreover, Applicants argued, "[A] person skilled in the art would have known that vascular cells cannot be expected to behave the same as tumor cells. In particular, tumor cells are understood to be abnormal cells characterized by uncontrollable growth properties. Accordingly, there is no certainty that results from the proliferation of tumor cells would be expected to apply to other types of normal cells."

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Contrary to Applicant's assertions, it is noted that Sells et al. was cited by the Examiner to provide evidence that the ordinary skilled artisan would have had knowledge of the potential role of Egr-1 in the regulation of cellular proliferation. Additionally, Sells et al. provides clear suggestion and motivation for using an inhibitor of Egr-1 to elucidate the role of Egr-1 in the regulation of cellular proliferation.

The examiner agrees that the following statement was made in the prior Office Action: "[M]endelsohn et al. does not explicitly describe a method of screening for compounds that inhibit proliferation of cells selected from vascular smooth muscle cells or endothelial cells, wherein the method specifically comprises determining the ability of a putative compound to inhibit induction of egr-1." In response to this statement Applicants argues that:

" The Examiner recognizes that Mendelsohn et al does not suggest assessing the ability of a putative compound to inhibit induction of Egr-1, decrease expression of Egr-1 or decrease the nuclear accumulation or activity of the Egr-1 gene product. Therefore, it is clear that step a) of the method of the invention is not contemplated by Mendelsohn et al."

However, contrary to Applicant's assertions, that was not the intended conclusion that the examiner intended to convey by this statement. The statement was made to convey the fact that the Mendelsohn et al. generically describes a method for identifying vasoprotective agents, which inhibit vascular smooth muscle activation and/or proliferation, and further wherein this reference describes a plurality of potential vassoprotective agents, wherein one among many targets described in this reference includes Egr-1. Mendelsohn et al. clearly provides motivation and suggestion for testing the ability of candidate inhibitors of Egr-1 to function as a vasoprotective agent

within the scope and context of the methods of Mendelsohn et al., wherein the methods involve screening methods that can be used to identify vasoprotective agents.

The teachings of Sells et al. were cited to provide evidence of the knowledge of inhibitors of Egr-1 in the art, and their potential role in the regulation of cellular proliferation. Although Applicants emphasize the fact that the inhibitors of Egr-1 described in Sells et al. were not used to treat normal cells, but were used to treat melanoma cells, it is clear that Sells et al. provide evidence of the ability of their compounds to inhibit Egr-1 expression, and further suggests to the ordinary skilled artisan that these compounds play a potential role in controlling cellular proliferation.

Moreover, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (see page 7, lines 5-9), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

It must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. (See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424) Contrary to Applicant's assertions, *absent evidence to the contrary*, one of ordinary skill in the art at the time of filing of the instant application seeking alternative means for

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identifying potential vasoprotective agents, and in view of the teachings of Mendelsohn et al., would have been motivated to test inhibitors of Egr-1 expression as candidate vasoprotective agents. Moreover, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Mendelsohn et al. with the teachings of Sells et al. in the design of the instant invention which comprises an additional step of testing the ability of the putative Egr-1 inhibitor to inhibit the proliferation of cells. One of ordinary skill in the art would have been motivated to make this modification since it is clear that the prior art teaches the function of Egr-1 in the regulation of cell proliferation as per the teaching of Sells et al., and further teaches that inhibitors of Egr-1 function to inhibit cellular proliferation.

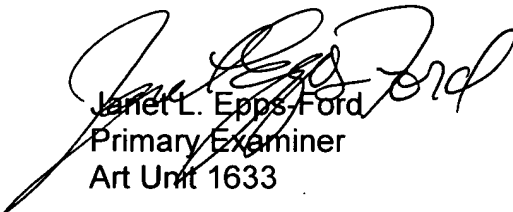
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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Janet L. Epps-Ford
Primary Examiner
Art Unit 1633

JLE